

version of the specification as originally filed, and a declaration of biological deposit. Support for the amendments to the specification, including the claims, may be found throughout the application as originally filed. No new matter is believed to have been introduced herein.

In response to the objections noted in paragraph nos. 8, and 10-12 of the present official action, the applicants, for the convenience of the examiner, have provided a substitute specification, addressing the objections raised by the examiner. As a further convenience to the examiner, the applicants have enclosed herewith a marked-up version of the specification (as originally filed) to show changes made. In view of the foregoing, the applicants request the withdrawal of the objections set forth in paragraph nos. 8 and 10-12 of the official action.

In paragraph no. 9 of the official action, the examiner objected to the abstract as originally filed alleging that the abstract does not completely describe the disclosed subject matter. The applicants submit that this objection is now moot in view of the foregoing amendment to the abstract. Therefore, the applicants request the withdrawal of this objection.

In paragraph nos. 13-15 of the official action the examiner objected to claims 1, 5, and 8 for minor informalities. By the foregoing amendment to the claims, the applicants submit that these rejections are now moot. Therefore, the applicants request the withdrawal of these objections.

Patentability Remarks

35 U.S.C. §112, Second Paragraph

At paragraphs 18-23 of the official action the examiner variously rejected claims 1-3, 5, and 8 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In claim 1, the phrase "from coryneform bacteria" is unclear as to its metes and bounds. Also with respect to claim 1, the examiner asserted that item c) in claim 1 is unclear

because it calls for a complementary sequence while the preamble of the claim requires the polynucleotide to "code for the citA gene" and the complement of a coding does not encode a gene. With respect to claims 1 and 2, the examiner alleged that the term "preferably" is unclear. Regarding claim 1, the examiner alleged that the language "activity of the sensor kinase CitA" is unclear; in that, allegedly, no activity is defined in the specification.

With respect to claim 5, the examiner alleged various deficiencies with respect to indefiniteness: (a) the phrase "within the range of degeneration of the genetic code" is unclear; (b) between items (iii) and (iv), the phrase "and optionally" is confusing and (c) in item (iv), the phrase "sense mutations of neutral function in (i)" is unclear.

Regarding claim 8, the examiner alleged that the indentations titled "8.1," "8.2," etc. are confusing. The Examiner suggests using --a--, --b--, etc. for clarity.

The applicants submit that in view of the foregoing amendment that these rejections are now moot. Specifically, with respect to claim 1, the language referred to by the examiner has been removed. With respect to claim 5, the claim now appears in independent form, while claim 8 has been amended as suggested by the examiner.

In view of the foregoing, the applicants submit that claims 1-3, 5, and 8 are neither vague nor indefinite and therefore request the withdrawal of the rejection of the claims based upon 35 U.S.C. §112, second paragraph.

35 U.S.C. §112, First Paragraph

Claims 1-3 and 5 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 is directed to polynucleotides having a particular, variable structure, having at least 15 nucleotides of a

polynucleotides that is at least 70% identity to a polynucleotide that encodes SEQ ID NO:2 while having no defined function. The phrase “codes for the *citA* gene” does not give a clear, functional limitation to the claims as noted above; the phrase “preferably having the activity of the sensor kinase CitA” also does not give a clear, functional limitation to the claims as noted above.

Claims 1-3 and 5 were also rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of enablement. It is the examiner’s position that because the specification, while being enabled for polynucleotides with at least, for example, 90% sequence identity to a polynucleotide that encodes SEQ ID NO:2, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the 70% identity claimed.

The examiner also rejected claim 8 under 35 U.S.C. § 112, first paragraph, enabling deposit, for a lack of a declaration of biological deposit.

The applicants respectfully traverse. With respect to claims 1-3 and 5 and in order to expedite prosecution and without prejudice to the applicants right to seek broader claims in a duly filed continuing application, the applicants have amended claims 1 and 5 to overcome the present rejection. With respect to the rejection of claim 8, the applicants note that a declaration of biological deposit, executed by the undersigned, is enclosed herewith.

In view of the foregoing, the applicants submit that the claims, as amended herein and in view of the declaration of biological deposit, are fully enabled and do not lack written description. Therefore, the applicants request the withdrawal of the rejection of the claims based upon 35 U.S.C. §112, first paragraph.

35 U.S.C. §102(b)

Claims 1, 2 and 4 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Mizuki *et al.* (GenBank Accession Number D84394. *Homo sapiens* genomic

DNA, 237 kb segment from 6p21.3 region including HLA genes, complete sequence. Published September 11, 1997). The instant claims are directed to DNA molecules having at least 15 consecutive nucleotides of SEQ ID NO:1 and that hybridizes to SEQ ID NO:1.

Mizuki et al. teach a DNA sequence wherein a 22-mer portion exactly matches SEQ ID NO:1 (see attached alignment). This DNA will hybridize to SEQ ID NO:1 by virtue of the natural affinity all DNA has for other DNA.


In response, the applicants submit that in view of the foregoing amendment to the claims, the rejection is now moot. Specifically, the language referred to by the examiner is no longer contained in the claims. Therefore, the applicants request the withdrawal of the rejection under 35 U.S.C. §102(b).

III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains at issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is strongly urged to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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Enclosures: Appendix
Substitute Specification – Marked-Up Version
Substitute Specification – Clean Version
Declaration of Biological Deposit



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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE

The title changes are noted in the attached Substitute Specification.

IN THE SPECIFICATION

The specification changes are noted in the attached Substitute Specification.

IN THE CLAIMS

The claims are amended as follows:

1. (Amended) An isolated polynucleotide [from] native to coryneform bacteria, comprising a polynucleotide sequence [which codes for the citA gene], [chosen] selected from the group consisting of:
 - a) a polynucleotide [which is identical to the extent of] at least [70%] 90%-95% identical to a polynucleotide [which codes for] that encodes a polypeptide [which comprises] comprising the amino acid sequence of SEQ ID NO:2[,]; and
 - b) a polynucleotide [which codes for] that encodes a polypeptide [which comprises] comprising an amino acid sequence [which is identical to the extent of] at least [to [sic] 70%] 90%-95% identical to the amino acid sequence of SEQ ID NO:2[,]
 - c) polynucleotide which is complementary to the polynucleotides of a) or b), and
 - d) polynucleotide comprising at least 15 successive nucleotides of the polynucleotide sequence of a), b),[sic] or c),

the polypeptide preferably having the activity of the sensor kinase CitA].
2. (Amended) A polynucleotide [as claimed in] according to claim 1, wherein the polynucleotide is a [preferably recombinant] DNA [which is capable of replication in coryneform bacteria].
3. (Amended) A polynucleotide [as claimed in] according to claim 1, wherein the polynucleotide is an RNA.

4. (Amended) A polynucleotide [as claimed in] according to claim 2, comprising the nucleic acid sequence as shown in SEQ ID NO:1.

5. (Amended) [A DNA as claimed in claim 2 which is capable of replication, comprising

- (i) the nucleotide sequence shown in SEQ ID no. 1, or
- (ii) at least one sequence which corresponds to sequence (i) within the range of the degeneration of the genetic code, or
- (iii) at least one sequence which hybridizes with the sequences complementary to sequences (i) or (ii), and optionally
- (iv) sense mutations of neutral function in (i).]

An isolated polynucleotide comprising SEQ ID NO:1.

7. (Amended) [A] An isolated polynucleotide [sequence as claimed in claim 2, which codes for] that encodes a polypeptide [which comprises] comprising the amino acid sequence [shown in] of SEQ ID NO:2.

8. (Amended) A vector pCR2.1citAint, [which] comprising:
- [8.1]a] [carries] an internal fragment of the citA gene having a length of 480 bp [in size, shown] as set forth in SEQ ID. NO:3,
 - [8.2]b] the restriction map of which is reproduced in figure 1[,]; and
 - [8.3]c] [which is] deposited in the E. coli strain Top10/pCR2.1citAint [at the Deutsche Sammlung für Mikroorganismen und Zellkulturen [German Collection of Microorganisms and Cell Cultures] under no. DSM 13998 [sic]] (DSM No. 13998).

9. (Amended) An internal fragment of the citA gene [with] having a length of 480 [bp, shown in SEQ ID No] basepairs as set forth in SEQ ID NO:3.

IN THE ABSTRACT OF THE DISCLOSURE:

The abstract is changed as follows:

[The invention relates to isolated polynucleotides comprising a polynucleotide sequence chosen from the group consisting of:

- a) polynucleotide which is identical to the extent of at least 70% to a polynucleotide which codes for a polypeptide which comprises the amino acid sequence of SEQ ID NO. 2,
 - b) polynucleotide which codes for a polypeptide which comprises an amino acid sequence which is identical to the extent of at least 70% to the amino acid sequence of SEQ ID No. 2,
 - c) polynucleotide which is complementary to the polynucleotides of a) or b), and
 - d) polynucleotide comprising at least 15 successive nucleotides of the polynucleotide sequence of a), b) or c),
- and a process for the fermentative preparation of L-amino acids using coryneform bacteria in which at least the *citA* gene is present in attenuated form, and the use of polynucleotides which comprise the sequences according to the invention as hybridization probes.]

--The present invention is related to nucleotide sequences encoding a sensor kinase, *citA*, from *Corynebacterium glutamicum*.--

End of Appendix